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May 7, 2020

Via Email

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RE: *In re Valsartan, Losartan and Irbesartan Products Liability Litigation*,
No. 1:19-md-02875 (Prioritized Discovery)

Counsel:

I write further to the Parties' telephonic meet-and-confer of May 5, 2020, regarding prioritization of discovery.

During the Parties' May 5, 2020 call, Defendants requested that Plaintiffs provide, in writing, a list of non-custodial documents which Plaintiffs requested be produced as soon as practicable, as well as information Plaintiffs required in order to prioritize custodial productions.¹

Non-Custodial Documents

Plaintiffs request that Defendants prioritize production of the below-delineated categories of non-custodial documents:

Contracts and Agreements

- Quality Supplier Agreements for the sale of Valsartan API (*See* RFPD Nos. 6, 10, 25, 96, 97, 98); and

¹ During the meet-and-confer, Plaintiffs made multiple efforts to gather information about what categories of non-custodial and custodial documents had already been collected, such that the prioritization requests could be accordingly narrowed or tailored. Plaintiffs made these inquiries for the purposes of efficiency and in an attempt to avoid needlessly wasting Defendants' resources, which Defendants have represented are scarce at this time. Defendants would not confirm what documents had been collected, beyond sales and pricing data. However, Defendants did assure Plaintiffs that any documents that are already collected will be produced first regardless of any prioritization made by Plaintiffs. As such, Plaintiffs provide the information in this letter with the understanding that Defendants will be producing *all* responsive documents currently in Defendants' possession by the July 15, 2020, Court-ordered deadline. *See* D.E. 416.

- Quality Supplier Agreements for services provided by solvent recovery vendors and outside laboratories used for the manufacture of Valsartan API or testing of Valsartan API (*See* RFPD Nos. 6, 119, 120).

API Manufacturing Quality Assurance Documents

- Deviation Investigation Reports for Valsartan API manufacture and any root cause analyses associated with those deviations (*See* RFPD Nos. 19, 20, 21, 22);
- OOS and OOT Reports for Valsartan API manufacture and any root cause analyses for those deviations (*See* RFPD Nos. 19, 20, 21, 22);
- Corrective and Preventative Action Plans (“CAPA”) implemented regarding the manufacture of Valsartan API (*See* RFPD No. 19, 20, 21, 211, 58); and
- Certificate of Analyses for Valsartan API (*See* RFPD No. 26).

Finished Dose Manufacturing Quality Assurance Documents

- Validation Specifications associated with Valsartan API (*See* RFPD Nos. 10, 19, 20, 21, 22);
- Certificate of Analyses associated with Valsartan API (*See* RFPD Nos. 10, 19, 20, 21, 22, 26); and
- OOS and OOT reports, and any root cause analyses, as a result of Valsartan API testing and/or validation (*See* RFPD Nos. 10, 19, 20, 21, 22).

Foreign Regulatory Documents

- Foreign Inspection Reports of Facilities which Manufactured Valsartan API or Finished Dose (*See* RFPD No 56, 57).

Custodial Documents

Plaintiffs are in the process of identifying priority custodians for all Defendants related to the following categories of responsive documents:

- Documents and communications related to the sale of API, including any quality issues and/or complaints related to API (such as, for example, ZHP’s communications with Novartis regarding the quality of Valsartan API and Novartis’s subsequent nitrosamine testing). *See* RFPD Nos. 6, 10, 25, 93, 96, 97, 98.
 - Plaintiffs have identified the following agreed-upon custodians as potentially having responsive documents:
 - **ZHP:** Jenson Ye, Min Li, Jucai Ge, Jie Wang;
 - **Mylan:** Satish Mahanti, Yasir Rawjee;
 - **Teva:** Stefan Karlsson, Jens Nassall, Corey Sawyer;
 - **Aurobindo USA:** Daniel Burns, Prasad Gorijavolu, Steve Lucas, Bhadresh Joshi; and
 - **Torrent:** Paras Sheth, Dhurmit Shah, Sushil Jaiswal.
- Documents and communications related to deviation reports, OOS/OOT and other quality assurance reports and investigations associated with API manufacture and/or testing. *See* RFPD Nos. 19, 20, 21, 22.
 - Plaintiffs have identified the following agreed-upon custodians as potentially having responsive documents:
 - **ZHP:** Jenson Ye, Min Li, Jucai Ge, Jie Wang, Zhao Caifeng, Dong Peng, Hu Yuelin, Li Qiangming;

- **Mylan:** Antonyraj Gomas, SVSJ Rama Varma, N. Anjani Kumar, K. Naveen Kumar, Yasir Rawjee, P. Srinivasa Rao;
 - **Teva:** Clarie Lyons, Dan Baretto;
 - **Aurobindo USA:** Daniel Burns, Jeffrey Jackowski, Bhadresh Doshi, Prasad Gorijavalu; and
 - **Torrent:** Paras Sheth, Dhurmit Shah, Sushil Jaiswal.
- Documents and communications with regulatory authorities, with special focus on regulatory communications regarding the cause of the contamination. See RFPD Nos. 52, 53, 54, 58, 59.
 - Plaintiffs have identified the following agreed-upon custodians as potentially having responsive documents:
 - **ZHP:** Jun Du, Jenson Ye, Xiaodi Guo, Lilje Wang, Remonda Gergis, Lucy Liu;
 - **Mylan:** Walt Owens, Reem Malki, Antonyraj Gomas, Cassandra Bird, Lance Molnar, SVSJ Rama Varma;
 - **Teva:** David Bonilla, Christopher Unger, Constance Truemper, Dan Baretto;
 - **Aurobindo USA:** Jasleen Gupta, Blessy Johns, Jeffrey Jackowski;
 - **Torrent:** Dawn Chitty, Sue Perry, Jocelyn Rivera, Bernadette Attinger, Saroja Garontla; and
 - **Hetero USA:** Seshu Akula, William Chelak, Rahhu Chigurupati, Somaraju Indukuri, Rajesh Kankula.
- Documents and communications related to the procurement of recovered solvents and/or the retention of outside companies to conduct solvent recovery. See RFPD Nos. 6, 119, 120.
 - Plaintiffs have identified the following agreed-upon custodians as potentially having responsive documents:
 - **Mylan:** M.V.R.B.S. Subrahmanyam, Abbineni Jyothibasu, N. Anjani Kumas; and
 - **Teva:** Corey Sawyer.

In order to finalize lists of prioritized custodians, for all the above-listed custodians, Plaintiffs request that Defendants identify which of these custodial files have been collected, and which have not yet been collected. Plaintiffs believe understanding this information will allow Plaintiffs to more narrowly tailor their custodial file prioritization, keeping these requests in line with Defendants' ongoing custodial collection efforts.

Plaintiffs are available to meet-and-confer further on these requests. Please advise us as to your availability.

Sincerely,

KANNER & WHITELEY, L.L.C.

By:



Layne C. Hilton

CC: Counsel for Manufacturer Defendants
Valsartan PEC